MAY 15 2014

510(k) SUMMARY

Date of Preparation: 11/ 8/ 2013

A. Submitter Information:

Submitter's Name: Medi-Globe Corporation

Submitter's Address: 110 West Orion Street #136
Tempe, Arizona 85283

Contact Person: Scott Karler

Contact Person's Telephone Number: (480) 897-2772 ext. 208

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Contact Person's Email Address: skarler@mediglobe.com

B. Proposed Device Information
- Trade Name: *SonoTip Pro and Pro Flex* EBUS-TBNA Needle System
- Common Name: Biopsy Needle Kit
- Classification Name: Gastroenterology-Urology Biopsy Instrument 21 CFR876,1075
- Product Code: FCG

C. Predicate Device:
- Trade Name: *SonoTip II* EBUS-TBNA Needle System
- Manufacturer: Medi-Globe, GmbH
- Clearance Number: K091257
- Common Name: Biopsy Needle Kit
- Classification Name: Gastroenterology-Urology Biopsy Instrument 21 CFR876.1075
- Product Code: FCG

D. Device Description:

The *SonoTip Pro and Pro Flex* EBUS-TBNA Needle System is a complete one-piece needle system for Fine Needle Aspiration and is a disposable instrument intended for single patient use only. The *SonoTip Pro and Pro Flex* EBUS-TBNA Needle System is coupled to the working channel of a legally marketed ultrasound endoscope. The needle is then ultrasonically guided and imbedded into the desired target lesion for aspiration of the required biopsy sample. A 2-way stop-cock valve and self-locking aspiration syringe are supplied as procedural aids to provide suction to through the needle lumen and assist in sample acquisition.

E. Intended Use:

Indications for Use: The *SonoTip Pro and Pro Flex* – TBNA Needle System is intended for Ultrasonically Guided Fine Needle Aspiration, (FNA) of submucosal and extraluminal lesions of the Tracheobronchial Tree and Gastrointestinal Tract, (e.g., lymph nodes, abnormal tissue in the mediastinum).

F. Technological Characteristics Summary:

The *SonoTip Pro and Pro Flex* EBUS-TBNA Needle System is identical when compared to Medi-Globe's own currently cleared device, *SonoTip II,* (K091257) utilizing endoscopic ultrasound technology which, when used with an ultrasound endoscope, allows the user to ultrasonically guide the biopsy needle to its intended target within or adjacent to the Tracheobronchial Tree or Gastrointestinal Tract. The proposed device is available with a new needle material composed of Nitinol, or with a stainless steel needle as is featured in the currently cleared device models. The Nitinol needle reduces deformation as the needle passes through the distal end of the working channel of some ultrasound endoscopes. In addition, the memory properties of Nitinol reduce deformation of the needle and help to retain the original linear alignment of the needle throughout the procedure.

G. Non-Clinical Performance Data:

Design verification data and biocompatibility testing has demonstrated that the proposed *SonoTip Pro and Pro Flex* EBUS-TBNA Needle System meets the same performance requirements and is as safe and effective as Medi-Globe's own currently cleared device, (K091257).

H. Conclusions of Non-Clinical Performance Data:

Medi-Globe Corporation has demonstrated that the proposed *SonoTip Pro and Pro Flex* EBUS-TBNA Needle System meets the same performance requirements and is as safe and effective as Medi-Globe's own currently cleared predicate device, (*SonoTip II* EBUS-TBNA Needle System, K091257). The *SonoTip Pro and Pro Flex* EBUS-TBNA Needle System is considered to have the same intended use, diagnostic/therapeutic effect, method of introduction/use, technical characteristics and general range of descriptive features as the predicate Medi-Globe *SonoTip II* EBUS-TBNA Needle System (K091257).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2014

Medi-Globe Corporation
Scott Karler
Regulatory Affairs Coordinator
110 West Orion Street, Suite # 136
Tempe, AZ 85283

Re: K133763
Trade/Device Name: SonoTip Pro and Pro Flex EBUS-TBNA Needle System
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: April 16, 2014
Received: April 21, 2014

Dear Scott Karler,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133763

Device Name: *SonoTip Pro and Pro Flex* EBUS-TBNA Needle System

Indications for Use: The *SonoTip Pro and Pro Flex* - TBNA Needle System is intended for Ultrasonically Guided Fine Needle Aspiration, (FNA) of submucosal and extraluminal lesions of the Tracheobronchial Tree and Gastrointestinal Tract, (e.g., lymph nodes, abnormal tissue in the mediastinum).

Prescription Use ☑ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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